

Summary of Risk Assessment Conducted Pursuant to subsection 83(1) of the *Canadian Environmental Protection Act, 1999*

New Substances Notification 20521: 1,2-Cyclohexanedicarboxylic acid, 1-(phenylmethyl) ester, ester with 2,2,4-trimethyl-1,3-pentanediol mono(2-methylpropanoate)] (Chemical Abstracts Service Registry Number 1661012-65-2)

Regulatory decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA), and pursuant to section 83 of the Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance, and have determined based on the available information, that when used as notified, the substance is not anticipated to enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential human health impacts that could arise as a result of potential new activities. [Order 2021-87-13-01 Amending the Domestic Substances List](#) outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 156, No. 1 on January 5, 2022. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

Substance identity

The notified chemical is 1,2-cyclohexanedicarboxylic acid, 1-(phenylmethyl) ester, ester with 2,2,4-trimethyl-1,3-pentanediol mono(2-methylpropanoate) (Chemical Abstracts Service Registry Number¹ 1661012-65-2).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as a plasticizer in sealants and artificial fabrics. Potential uses may include use of the substance in consumer products and cosmetics and in Canadian manufacturing.

Environmental fate and behaviour

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Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to sediment and water. The substance is not expected to be persistent in this compartment based on moderate ready biodegradation (30-60% over 28 days) and moderate atmospheric half-life (2-12 hours). The substance is not expected to bioaccumulate based on a low measured bioconcentration factor (<250 L/kg) for an analogue substance.

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity to fish (no adverse effects observed in saturated solutions), and is expected to have moderate acute toxicity to aquatic invertebrates (median effective concentration (EC₅₀) 1-100 mg/L) and moderate chronic toxicity to aquatic invertebrates and algae (10% effective concentration 0.1 – 10 mg/L). Using the EC₅₀ from the most sensitive organism (aquatic invertebrates) and by applying an appropriate assessment factor of 250 to account for acute to chronic extrapolation, species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1-10 µg/L, which was used to estimate the risk to the environment.

The environmental exposure of the notified substance was evaluated as read-across from data available for similar substances. Significant environmental monitoring for medium chain phthalates reported concentrations in surface waters ranging between 0.003 and 2.0 µg/L, when detected. No potential activities that could significantly increase environmental risks compared to those notified were identified.

Comparing the predicted environmental concentration with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that the substance is unlikely to cause harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral and dermal routes (median lethal dose > 2000 mg/kg body weight). The substance is expected to have a moderate systemic subchronic toxicity and a high developmental toxicity following repeated oral doses in mammalian test animals (no-observed-adverse-effect level (NOAEL) 30-300 mg/kg-bw/day). It is considered to have low reproductive toxicity. It is not a dermal sensitizer (stimulation indices < 3 to produce a response (local lymph node assay)). It is not expected to be mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be in the range of 100-1000 µg/kg bw/day based on the NOAEL of the oral subchronic/reproductive/developmental toxicity study in mammalian test animals. The PTDI is the estimated level of long-term exposure without risk of adverse health effects.

When the notified substance is used as a plasticizer in the manufacture of sealants and coated fabrics, consumers may come into contact with end-use products containing the substance.

Although the substance may migrate at low levels from the cured matrix, direct exposure to the substance will be limited by the frequency and duration of exposure, as well as the limited capacity for dermal absorption. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels given the low potential for release to the environment. However, if the substance is used in consumer products and cosmetics, increased levels of direct and indirect exposure may exist, and is expected to be sustained by dermal contact and ingestion resulting in a total combined exposure at levels in the range of 1-100 µg/kg bw/day. There is increased potential for exposure of infants and young children to the substance if it finds use in toys and children's articles. Exposure would be expected to occur via the oral route when young children chew, suck and bite these products, regardless of whether the products are intended to be mouthed. Oral exposure for infants via the mouthing of toys is expected to be in the range of 100-1000 µg/kg bw/day.

Based on the low potential for exposure when used as notified, the substance is not likely to pose a significant health risk to the general population, and is therefore unlikely to be harmful to human health.

However, based on the potential for increased oral and dermal exposure combined with indications that the substance has developmental toxicity, the potential use of the substance in consumer products and cosmetics could significantly alter the exposure and/or conditions of use resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

Assessment conclusion

When the substance is used as notified, it is not suspected to be harmful to human health or the environment according to the criteria under section 64 of the Act. However, it is suspected that a significant new activity in relation to the substance could result in the substance meeting those criteria.

Due to the potential risk to human health related to developmental toxicity if the substance is potentially used in consumer products, the SNAC provisions under CEPA were applied to the substance in order to obtain information to ensure that the substance undergoes further assessment before these potential activities are undertaken. Order No. 2021-87-13-01 was published in the *Canada Gazette* Part II, Vol. 156, No. 1 on January 5, 2022.

A conclusion under CEPA, on this substance, is not relevant to, nor does it preclude an assessment against the hazard criteria for Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or the *Hazardous Products Regulations* for products intended for the workplace.